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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,454	09/14/2000	Masayuki Yanagi	2026-4276US1	9114

7590 05/19/2004

KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street
14th Fl.
Irvine, CA 92614

EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,454	YANAGI, ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,45-53 and 55-57* is/are pending in the application.

4a) Of the above claim(s) *46,47,49 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42, 45, 48, 51-53 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/2003 has been entered.

In the response filed on 9/25/2003 several claims were amended (claims 42, 48, 51, 53 and 55-56) and claim 43 was cancelled. Claims 42, 45-53 and 55-57 are pending, with claims 46, 47, 49 and 50 withdrawn from consideration as being drawn to non-elected inventions.

Response to Amendment

The claims have been amended to delete the term "pharmaceutical" from the claims, broadening the scope of the claims to include embodiments where the composition comprising a nucleic acid that encodes the polypeptide comprising the sequence of the unprocessed human hepatitis C virus described by SEQ ID NO: 3 is used to elicit an immune response from an animal (e.g. an antibody against the polypeptide). This change has resulted in the withdrawal of the grounds of rejection made in the previous actions with regard to enablement under 35 U.S.C. 112 1st paragraph for treatment claims using the compositions of the invention. Applicants have demonstrated that the nucleic acid compositions of their invention can produce antisera against the polypeptide encoded by the nucleic acid (e.g. the specification at Figure 18B and Example 4A; post-filing 1998 Yanagi et al reference at Figure 9). The deletion of the term

"pharmaceutical" and "immunizing" has necessitated the following rejection on the grounds of obviousness-type double patenting.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42, 45, 48 and 51-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 9, 19-20 and 22 of U.S. Patent No. 6,153,421. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. **This is a new rejection, necessitated by applicants' amendment of the claims in the response filed 9/25/2003.**

The claims of the instant application are drawn towards compositions comprising a purified and isolated nucleic acid molecule encoding a human hepatitis C virus propeptide described by SEQ ID NO: 3. The nucleic acid can encode a wildtype virus or a chimeric virus wherein a fragment of the viral genome is replaced with the corresponding fragment from a different strain of hepatitis C virus, so long as the nucleic acid still encodes SEQ ID NO: 3. The

fragment can either encode the structural proteins of the hepatitis C virus or can encode any protein from the hepatitis C virus. The nucleic acid can comprise SEQ ID NO: 4.

The claims of the '421 patent are drawn towards purified and isolated nucleic acid molecules, wherein the nucleic acid molecules encode human hepatitis C virus and wherein expression of the nucleic acid molecules in transfected cells results in production of virus when transfected in cells (e.g. where the nucleic acid encodes SEQ ID NO: 3). The nucleic acids can encode a wildtype virus or a chimeric virus wherein a fragment of the viral genome is replaced with the corresponding fragment from a different strain of hepatitis C virus. The fragment can either encode the structural proteins of the hepatitis C virus or can encode any protein from the hepatitis C virus. The nucleic acid can encode the amino acid sequence of SEQ ID NO: 3. The nucleic acid can comprise SEQ ID NO: 4.

The major difference between the instant claims and the claims of the '421 patent is that the issued claims stipulate that when the nucleic acid compositions are introduced into cells, production of virus necessarily results. Applicants have demonstrated in their specification that the nucleic acids of their invention that are capable of producing virus upon infection into the cells of an animal also produce an antibody response against the polypeptide(s) encoded by the nucleic acid of the composition. Therefore, the issued claims encompass narrower embodiments of the nucleic acid compositions of the invention that anticipate and necessarily make obvious the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 51-53, 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection, necessitated by applicants' amendment of the claims in the response filed 9/25/2003.**

Claim 48 recites that the nucleic acid of the invention encodes the polypeptide having the sequence of SEQ ID NO: 3, but further states that a portion of the nucleic acid molecule encoding a "structural region" of the hepatitis C virus has been replaced with a portion of a nucleic acid molecule of a different hepatitis virus that encodes the corresponding structural region. Claim 51 recites a similar limitation where the portion that has been substituted encodes at least one HCV protein from a different hepatitis C virus. Claim 53 recites that the substituted portion encodes all or part of an HCV protein. Since hepatitis C viral nucleic acids comprise a single open reading frame encoding a single polypeptide from which the other viral polypeptides are obtained, and since the claims are necessarily limited to those nucleic acids that encode SEQ ID NO: 3, it appears that the claims are directed to embodiments where the nucleic acid sequence may be hybrid in nature, yet the polypeptide encoded is the same (e.g. for codon optimization). However, upon reading the specification it does not appear that the *chimeric* nucleic acids of the invention are directed to chimeric nucleic acids encoding the exact same protein sequence but are actually directed to embodiments that encode chimeric polypeptides (i.e. rather than just SEQ ID NO: 3 as is recited in the claims). For these reasons, it is unclear as to what is encompassed by the rejected claims. It would be remedial to amend the claims to clearly indicate whether the recited chimeric nucleic acids necessarily only encompass embodiments where the single

propeptide encoded by the nucleic acid is SEQ ID NO: 3, or can also encode chimeric polypeptides.

Conclusion

No claims are allowed. Claims directed to nucleic acid compositions encoding a human hepatitis C virus polypeptide having the amino acid sequence of SEQ ID NO: 3 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

GERRY LEFFERS
PRIMARY EXAMINER